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| **Application ID (as it appears in the application form / change notification form)** |
|  |

* [X] in this document indicates a document to be named including page number – submitted for evidence. Grey text (for guidance) may be replaced/deleted.
* In case of a Change Notification, please only fill in the applicable sections.

# Short Product Description relevant for Ethylene Oxide Sterilization

Note: Please replace italic text with respective information

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| **Short description incl. picture of the device** - in case of changes, as far as relevant |
| Description of the device as far as relevant for sterilization (pictures for clearer understanding):*To be added**Product schematic and / or photo of product, size, material, Intended Use / Intended Purpose according to IFU (inclusive total application duration, body contact, implantable, patient group), packaging description, picture*Variants under assessment: *To be added**Product variants (e.g. Same product in different SBS, multiple products in same SBS)**Description of the Sterile Barrier System specifications used at sterilization* |

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| **Has this product previously been assessed by TÜV SÜD Product Service?** |
| *If yes, please provide 10-digit order no. usually starting with 071xxxxxxx, or equivalent traceable information* |

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| **Manufacturing facility and certification status of the applicable sterilization sites / facilities** |
| *Manufacturing site to be named* | *Please provide the applicable QMS Certificate 13485 of the used sterilization site* |
| *Sterilization site to be named* | *Please provide the applicable QMS Certificate 13485 of the used sterilization site* |

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| **External laboratories if used for sterilization validation and certification status of the laboratory** |
| *Name of the laboratory* | *Please name the test done by the laboratory (e.g. microbiology BI testing, sterility testing, bioburden, EO residuals). Please provide the applicable QMS accreditation certificate (e.g. ISO 17025 or GLP)*  |
| *Name of the laboratory* | *Please name the test done by the laboratory (e.g. microbiology BI testing, sterility testing, bioburden, EO residuals). Please provide the applicable QMS accreditation certificate (e.g. ISO 17025 or GLP)*  |

# Production related Information

## Equipment Specification

Note: Please replace italic text with respective information. Please add additional lines if required.

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| **Equipment including Identifier (e.g. int. ID/ serial number)** | **Site** | **Applicable cycle operated by the equipment for the device in question** | **Type of cycle**  | **Usable chamber volume in m3** | **All sensors / measurement devices (internal + external sensors, dataloggers for validation) are calibrated (statement sufficient)** |
| *e.g. Preconditioning (if applicable)* | *Inhouse or external source* | *Please name the cycle and version/ revision of cycle* |  | *8* | [ ]  Yes[ ]  No |
| *e.g. Sterilizer A10* | *Inhouse or external source* | *Please name the cycle and version/ revision of cycle* | *e.g. (overpressure, underpressure)* | *5,4* | [ ]  Yes[ ]  No |
| *e.g. Venting Tunnel* | *Inhouse or external source* | *e.g. program #3 rev11* |  | *30* | [ ]  Yes[ ]  No |
|  |  |  |  |  |  |

## If Applicable: Cleaning of Product in Manufacturing before Sterilization

Note: Please replace italic text with respective information. Please add additional lines if required.

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| **Cleaning process description** |
| Are cleaning parameters that are specific for the medical device defined? | [ ]  yes documented in *[X,p.y]*  [ ]  no *please justify:*Please describe the cleaning process:*Parameters of the cleaning process may be specific load configuration, positioning, connection, accessories, process chemicals, pressures or temperature limit(s)…* |
| Were cleaning studies performed at validation of the used equipment to approve the respective cleaning process step is able to deliver appropriate performance? | [ ]  yes documented in *[X,p.y]*  [ ]  no *please justify:**Cleaning studies shall reflect the potential contamination and evidence of reproducible elimination of the contamination to a safe level (see EN ISO 17664)* |
| Are process residuals within limits? | [ ]  yes documented in *[X,p.y]*  [ ]  no *please justify:**Residuals like endotoxins, particles, org. inorganic contaminations, detergent residues with adequate risk related to the device and body contact shall be safe and acceptable.* |
| Are preventive maintenance operations defined including frequencies? | [ ]  yes documented in *[X,p.y]*  [ ]  no *please justify:**Examples for preventive maintenance are: exchange of cleaning media and/or equipment* |

## If Applicable: Disinfection of Product in Manufacturing before Sterilization

Note: Please replace italic text with respective information. Please add additional lines if required.

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| **Disinfection process description** |
| Are parameters that are specific for the medical device defined, such as specific load configuration, positioning, connection, accessories, process chemicals, pressures or temperature limit(s)? | [ ]  yes documented in *[X,p.y]*  [ ]  no *please justify:*Please describe the disinfection process:*Parameters of the disinfection process may be specific load configuration, positioning, connection, accessories, process chemicals, pressures or temperature limit(s)…* |
| Were disinfection studies performed at validation of the used equipment to approve the respective disinfection process step is able to deliver appropriate performance? | [ ]  yes documented in *[X,p.y]*  [ ]  no *please justify:**Disinfection studies shall reflect the potential contamination and evidence of reproducible elimination of the contamination to a safe level (see EN ISO 17664)* |
| Are process residuals within limits? | [ ]  yes documented in *[X,p.y]*  [ ]  no *please justify:**Residuals like endotoxins, particles, org. inorganic contaminations, detergent residues with adequate risk related to the device and body contact shall be safe and acceptable.* |
| Are preventive maintenance operations defined including frequencies? | [ ]  yes documented in *[X,p.y]*  [ ]  no *please justify:**Examples for preventive maintenance are: exchange of disinfection media and or equipment* |

## If Applicable: Clean Room Control / Validation

Note: Please replace italic text with respective information. Please add additional lines if required.

This section is applicable to be filled in case of first evaluation of the clean room or in case of changes occurred to the clean room (e.g. new clean room, modification of the cleanroom and changes to the setup of the points listed in the table below).

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| Cleanroom | *Please identify the cleanroom(s) where the manufacturing takes place, including ISO classification* |
| Are action and alert levels/limits set appropriately for the subsequent product bioburden in cleanroom processes? | [ ]  yes documented in *[X,p.y]*  [ ]  no *please justify:*Acceptance criteria for “in operation” condition:Airborne particles [*size*]: particles/m3Airborne microbiological contamination: cfu/m3 *(and/or settle plates)*Surface microbiological contamination: cfu/ surface areaProduct bioburden: cfu *(type – spores, fungi, anaerobe, bacteria) The bioburden shall be known to a degree to make decisions on resistance* |
| Monitoring points are defined for the above-mentioned measurements | [ ]  yes documented in *[X,p.y]*  [ ]  no *please justify* |
| Was IQ, OQ, PQ of the cleanroom successfully established? | [ ]  yes documented in *[X,p.y]*  [ ]  no *please justify:* |
| Is all measuring equipment in a calibrated state? | [ ]  yes documented in *[X,p.y]*  [ ]  no *please justify:* |
| Are utilities and media under surveillance | [ ]  yes documented in *[X,p.y]*  [ ]  no *please justify:**Please specify what media and related acceptance criteria are defined.**e.g. for water, compressed air…* |
| Are environmental parameters defined: | [ ]  yes documented in *[X,p.y]*  [ ]  no *please justify:*Please specify - where applicable:Temperature: Humidity:Pressure gradient / pressure level at each room:Air change rates: |

## Cycle Specification

Note: Please replace italic text with respective information for inhouse and outsourced processes.

Please add additional lines if required.

**Please paste copy of the cycle specification used at routine sterilization:**

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| --- |
| *Please paste here* |

|  |  |
| --- | --- |
| Is resterilization allowed? | [ ]  Yes*Please name the amount of re-sterilizations allowed*[ ]  No |
| Was product functionality verified after maximum amount of allowed sterilization cycles | [ ]  Yes, documented in *[x]* [ ]  No, *please justify*: |

## Basic Validation Development Data

Note: Please replace italic text with respective information.

|  |  |
| --- | --- |
| Validation Method | [ ]   overkill half cycle approach (EN ISO 11135 Annex B 1.2.a)[ ]   overkill cycle calculation approach (EN ISO 11135 Annex B 1.2b)[ ]   BI and bioburden (EN ISO 11135 Annex A 1.3 b,c)[ ]   Bioburden (EN ISO 11135 Annex A 1.3 a)[ ]   Product adoption to an existing cycle:*Please assure that the adoption rationale and MPQ/PPQ validation data are submitted for the predicate device. This data is documented in [X]*[ ]   Other: *Please specify and add rationale for not using a standardized method* |
| Revalidation criteria | [ ]   By what events is a new validation is triggered - *is documented in [X]**Please provide the review interval of data, and interval of time till repeat MPQ / PPQ studies. When was the last MPQ, PPQ study executed?**What are further criteria that to trigger a revalidation study (e.g. product changes…)?*[ ]   Validation protocol for the actual sterilization cycle including acceptance criteria - *is documented in [X]* |

## MPQ

Note: Please replace italic text with respective information for inhouse and outsourced processes. Please add additional lines if required.

**Please paste copy of the cycle specification used at validation of sterilization MPQ:**

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| --- |
| *Please paste here. Cycle record summaries are documented in [X]* |

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| **MPQ Processing - Microbial Performance Qualification** |
| Biological indicators (if applicable) | [ ]   Specification of Biological Indicators (BI) used is provided *This data is documented in [X]**Placement scheme and number of BIs or spore suspension, BI certificate* [ ]   Parametric release*Placement of reference sensor(s)* |
| BI results including culture conditions and time between end of cycle and BI testing | [ ]  Sublethal cycle for BI resistance was performed – if no *please justify:*[ ]  BI results including culture conditions and time between end of cycle and BI testing is documented in *[x]* |
| IPCD/EPCD (if applicable): | [ ]  Drawings or pictures including place of inoculation position is provided in the submission *including rational for the position and type taking into account: challenge to bioburden, physical conditions in load and diffusion pathways. This data is documented in [X]* |
| [ ]  Data on the relationship of the resistance between EPCD, IPCD, worst-case Products, natural Bioburden are provided. *This data is documented in [X]* |
| Bioburden | *Please specify the bioburden level/limits e.g. in respect to bacteria, yeast/molds and anaerobic bacteria (were these investigations at least part of the initial assessment of bioburden)**Please provide the bioburden trending data as a summary of the last year, if not available at least for the validation LOT.**Please specify further for the environmental controlled manufacturing area the control limits for airborne bioburden and particles.* |
| Is endotoxin testing applicable for the device under assessment? | [ ]  no  [ ]  yes [X,p.y]*Please specify the method and related results. The data is documented in [X].* *(e.g. in case of direct contact to blood, CNS / CSF, eye or other systemic exposure)* |

## PPQ Physical Performance Qualification

Note: Please replace italic text with respective information for inhouse and outsourced processes. Please add additional lines if required.

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| Please specify the validation load configuration: | Please specify the load used during validation at PPQ and MPQ:*Please consider min and max configuration in case of widely varying load configurations, scheme of total load), number of BIs, number of sensors (T and rH), scheme of position of BIs, total load volume, density, amount of adsorptive material (EO and water) (EN ISO 11135 9.4). The data is documented in [X]* |
| Please specify which product was used in the load: | The product is the same as in section 1[ ]  yes [X,p.y]   [ ]  no *– Please provide a description and justification*  |

**Please paste copy of the cycle specification used at validation of sterilization PPQ:**

|  |
| --- |
| *Please paste here covering all of section 11135 9.5.4 The data is documented in [X]* |

**Please assure that the following phases and process values and tolerances are part of the all over validation requirement.**

Please be aware that the below parameters are not exhaustive to cover the cycle, cycle and load types, but are often omitted causing deficiencies and are thereof specifically requested.

|  |  |  |  |
| --- | --- | --- | --- |
| **Phase** | **Acceptance criteria: values and tolerance** | **Results measured acc. 11135 9.5.4** | **Comments if needed** |
| Preconditioning: | *Min/Max load temperature and humidity at end of preconditioning* | *To be added* | *To be added if any* |
| Conditioning | *Min/max load temperature and humidity during and end of conditioning* | *To be added* | *To be added if any* |
| Sterilization/Exposure phase | *Load temperature* | *To be added* | *To be added if any* |
| The achievement of all cycle specification data and parameters above is verified during validation covering all of EN ISO 11135 9.5.4: | [ ]  Yes, documented in *[x]**(best provided in a table showing setpoint/tolerances against measured data)*[ ]  No, *please justify:* |  | *To be added if any*  |
|  |  |  |  |

# EO / ECH Residuals

Note: Please replace italic text with respective information for inhouse and outsourced processes.

Please add additional lines if required.

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|  |  |  | **Comments** |
| Is a rationale provided for selection of representative sample(s) | [ ]  Yes, documented in *[X]* | [ ]  No, *please justify*: | *To be added if any*  |
| Are the applicable Allowable limits for EO/ECH for the product in question considering the patient population provided | [ ]  Yes, documented in *[x]* | [ ]  No, *please justify:* | *To be added if any*  |
| Results and test method provided | [x]  Yes, documented in *[x]* | [ ]  No, *please justify:* | *To be added if any*  |

# Routine Processing

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| **Routine Processing** |
| Please provide the EO-gas specification: | *Please name the supplier of the EO gas and EO gas specification* |
| Routine release | [ ]  BI and physical parameters*Placement scheme and number of BIs, BI certificate or spore suspension*[ ]   Parametric release*Placement of reference sensor(s)* |
| Release criteria documented in *[x]:**e.g. comparison of validation plot to routine plot, BI negative* |
| Placement scheme and number of BIs, BI certificate provided? | [ ]  Yes, documented in *[x]*[ ]  No, *please justify:* |
| Routine cycle control and regulation is achieved by: | [ ]  Chamber fixated sensors only[ ]  Product integrated sensors (e.g. simulated product with integrated sensor) |
| Load configuration | [ ]  Dedicated load *Product configuration is fixed in number and location within chamber*[ ]  Mixed load*different products allowed*Please add information on min/max load variation, if applicable: |

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*Note as to the signature’s relevance: If this document is officially signed, the provided rationales and data herein can be officially used by the reviewer. Otherwise, only the referenced documents can be used as evidence*